510(K) Summary

Submitter
CSM Implant
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Device Information

Trade Name: CSM submerged-R Implant System

Common Name: Endosseous Dental Implant

Classification Name: Implant, Endosseous, Root-Form

Product Code: DZE

Regulation Number: 872.3640

Device Class: Class II

Date Prepared: Aug, 2010

General Description

The CSM submerged-R implant system includes various one-stage Fixtures and two-stage Fixtures made of titanium. These implants are surgically inserted into the upper jaw and/or lower jaw and serve as a tooth root replacement providing a stable foundation for restorations.

This product is a fixture and an abutment prosthetic dentistry material which are dental implant infrastructures. The connection with the abutment is inserted in bones as internal connection (the morse taper 11° and Hexagon type) method. A connection will restore mastication function of the patient who has difficulties due to damage of the natural tooth and function as a supporting the prosthetic dentistry material such as artificial tooth.

Indication for Use

The CSM submerged-R Implant System is especially designed for use in dental implant surgery. According to the widely accepted clinical studies successful osseointegration between fixture and the live bone depends on surgical implantation under proper conditions, shape of fixture and surface treatment technique. Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. In case of Customized Hand Milling Abutment, its wall thickness is 2mm and height is 12mm. It can be reduced into Max. 7mm. The margin of the product can be modified up to Max 20°. In case of Non-Hex Cementation Abutment, it is a bridge type. Two or more products must be used. Under part of abutment is made in round shape in order to avoid restriction in connecting work.

K111120

Predicate Devices & Comparison

The subject device is substantially equivalent to the following predicate device:

- SQ IS System manufactured by Neobiotech Co., Ltd. (K090825)

Testing and other comparisons have established that the subject of CSM submerged-R Implant System is substantially equivalent in design, materials, indications and intended use, packaging, labeling, and performance to other predicate devices of the type currently marketed in the U.S.

Comparison Chart

	Subject Device	Predicate Device
510(K) Number	N / A	K090825
Device Name	CSM submerged-R Implant System	SQ IS System
Manufacturer	CSM Implant	Neobiotech Co., Ltd.
Indications for Use	Mandible and Maxilla Endosseous Dental Implant & Accessories	Mandible and Maxilla Endosseous Dental Implant & Accessories
Design	Submerged Implant Design	Submerged Implant Design
Implant Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma
Surface Treatment	RBM (Resorbable Blasting Media)	RBM (Resorbable Blasting Media)
Implant Diameters	3.52 ~ 5.32 mm	3.5 ~ 8.0 mm
Implant Lengths	8 ~ 14 mm	7 ~ 15 mm
Abutment diameters	4.0 ~ 6.5 mm	3.5 ~ 8.0mm
Abutment lengths	5.5 ~ 7.5mm	4.0 ~ 8.0mm
Attachments	Various abutments and components	Various abutments and components
Implant material	Ti-6Al-4V ELI ASTM-F136	Ti-6Al-4V ELI ASTM-F136
Cover Screw Material	CP. Ti. Gr. 4 ASTM-F67	CP. Ti. Gr. 4 ASTM-F67
Product Code	DZE, NHA	DZE, NHA

Substantial equivalence chart summary

The CSM submerged-R Implant System has a substantially equivalent intended use as the identified predicate, SQ IS System (K093321) manufactured by Neobiotech Co., Ltd. and is made of titanium metal intended to be surgically placed in the bone of the upper or lower jaw arches. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. CSM submerged-R Implant System and predicate device are made from pure titanium and the surface treatment is done with RBM.

These predicate devices and CSM submerged-R Implant System have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutment. The subject and predicate devices are similar in size, surface treatment, and both are sterilized via gamma irradiation. When compared with predicate devices, no new questions of safety or effectiveness have been raised for the CSM submerged-R Implant System.

Performance Data

All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004, mechanical testing of the implants demonstrated that the CSM submerged-R Implant System possess mechanical strength at least equivalent to the predicate devices.

Among the information and data presented in this 510(k) submission to support the substantial equivalence of the CSM submerged-R Implant System to the specified predicate devices, fatigue testing demonstrated that there is substantial equivalence in the performance, safety and effectiveness between the CSM submerged-R Implant System and the referenced predicate devices. Fatigue testing also demonstrated that this system meets its predefined acceptance criteria and performs in accordance with its intended use.

Safety and Effectiveness

CSM submerged-R Implant System is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device. The CSM submerged-R Implant System, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

Conclusion

The CSM submerged-R Implant System, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or safety risks to patients when used as intended. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, CSM submerged-R Implant System and its predicate devices are believed to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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OCT 14 2011

Re: K111120
Trade/Device Name: CSM submerged-R Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 27, 2011
Received: October 3, 2011

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K111120

Device Name: CSM submerged-R Implant System

The CSM submerged-R Implant System is especially designed for use in dental implant surgery. According to the widely accepted clinical studies successful osseointegration between fixture and the live bone depends on surgical implantation under proper conditions, shape of fixture and surface treatment technique. Implants are intended for use in support of single or multiple-unit restorations and partial or fully edentulous mandibles and maxilla. In case of Customized Hand Milling Abutment, its wall thickness is 2mm and height is 12mm. It can be reduced into Max. 7mm. The margin of the product can be modified up to Max 20°. In case of Non-Hex Cementation Abutment, it is a bridge type. Two or more products must be used. Under part of abutment is made in round shape in order to avoid restriction in connecting work.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111120